APR 12 2011

510(k) Summary

Submitter:

MedVoxel Systems Inc.

7363-515 W. Hastings Street
Vancouver, British Columbia
Canada V6B 5K3
Phone: (604)889-3512/(778) 960-5401
Web: www.medvoxel.com

Contact:

Bonnie Sewlochan

Regulatory Consultant on behalf of ***MedVoxel Systems Inc.***
2867 Crosscurrent Drive, Mississauga
Ontario, Canada L5N 6L1
Phone: (647) 234-6643

Device Name:

Trade Name	MedVoxel HeartPro Software Application
Common Name	Cardiovascular Image Analysis Software
Classification	System, Image Processing, Radiological
CFR Section /Product Code	21 CFR 892.2050, LLZ
Device Class	Class II
Date of Preparation of Summary:	March 28, 2011

Predicate Device

Trade Name	510(k) Submitter/Manufacturer	510(k) Number	Date Cleared
Leonardo Syngo Cardiology Workstation (Argus)	Siemens Medical Solutions Inc. 51 Valley Stream Parkway Malvern, PA 19355	K042203	September 24, 2004

Device Description

MedVoxel is a software company that focuses primarily on cardiac specific, clinical post-processing packages and has made it their mandate to offer a product solution that will allow the user to manipulate the image set such that the background phase and phase aliasing errors can be minimized if not eliminated from the images.

MedVoxel HeartPro is a web-accessible, self-contained image analysis software application. The application uses cardiac-specific MR scans as a data source for their blood flow analysis computations.

Pre-existing MR images are sent from the PACS (or scanner) to the MedVoxel HeartPro software application, image corrections (specific to aliasing errors) are applied to the set of images prescribed by the user, contour are placed and advanced analysis algorithms are applied. Easily reproducible test results are produced and stored in the Measurement Record of the patients' study.

HeartPro does not interface directly with any MR or data collection equipment; instead HeartPro imports data files previously generated by such equipment.

HeartPro provides quantitative measurements specific to blood flow analysis for MRI data sequences. The software application focuses on what is visible to the eye and applies advanced automated methods to avoid tedious, time-consuming manual methods. The software does not perform any functions which cannot be accomplished by a trained user utilizing manual tracing methods; the intent of the software is to save time and automate potential error-prone manual tasks.

The software has functions for loading, analysing, saving datasets and will generate screen displays, computation and aggregated statistics.

Intended Use

HeartPro consists of software that analyzes DICOM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. ***HeartPro*** specifically analyzes the blood flow to the heart and its major vessels using multi-slice, multi-phase and velocity encoded MR images. It provides clinically relevant and reproducible, quantitative data and has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners.

The data produced by ***HeartPro*** is intended to be used to support qualified cardiologist, radiologist or other licensed professional healthcare practitioners for clinical decision making. It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.

Comparison to the Predicate

The intended use and technological characteristics of the MedVoxel HeartPro software application are substantially equivalent, in the opinion of MedVoxel Systems, to those of the predicate device and do not pose any new issues of safety and effectiveness. A comparison table has been included on the next page.

TABLE: Comparison of features and specifications of HeartPro vs. Predicate Device

Device Feature	MedVoxel *HeartPro*	Siemens *Argus*
510(k) Number	K103565	K042203
Overview		
DICOM compliance	Supports DICOM 3.0	Supports DICOM 3.0
Comparative review	2D	2D
2D measurements	ROI tools with statistics	ROI tools with statistics
Workflow	Automated contouring Automated measurements Manual correction.	Automated contouring Automated measurements Manual correction.
GUI Interface/Input/output		
Image input	DICOM 3.0 via TCP/IP DICOM via secure FTP	DICOM 3.0 via TCP/IP
Data Acquisition Protocol for Blood 'ow Analysis	Cardiovascular images (specifically, multi-phase, multi-slice and velocity encoded images acquired from magnetic resonance scanners). Same approach to general usage - performs Blood Flow calculations, and output the desired data parameters.	Cardiovascular images (specifically, multi-phase, multi-slice and velocity encoded images acquired from magnetic resonance scanners). Same approach to general usage - performs Blood Flow calculations, and output the desired data parameters.
User Interactions	Users can browse, select, and load CMRI scan files. Users can save and load analyses, export to files. User can generate a report that displays quantitative data items and can be saved to a PDF file. DICOM info displayed.	User can browse, select, and load CMRI scan files. User can save and load analyses, export to files. User can generate a report that displays quantitative data items.
Measurement information page	Blood flow chart displayed	Blood flow chart displayed
Repeatability	Re-enter the parameters recorded in the previously made reports. Fully repeatable when relying on automated ROI definition. If manually defined - Not easily reproducible (identical to predicate) due to significant manual involvement.	Not easily reproducible due to significant manual involvement

Contouring/Editing		
ROI vessel contour detection	Automatic contour detection with user input (optional: can be followed by manual user editing).	Automatic contour detection without initial user input followed by manual user editing
ROI vessel contour editing	Contour editor	Contour editor
Analytical Processing /Quantitative Outputs		
Phase aliasing error correction	Phase alias correction provided via user interface	Phase alias correction provided via user interface
	Measurement algorithm generates quantitative clinical data, including parameters such as net blood flow rate, and blood flow volume.	With manual assistance, measurement algorithm generates quantitative clinical data, including parameters such as net blood flow rate, and blood flow volume.
Screen Functions and Image Manipulations		
Feature Sets	Extensive set of features for image manipulation, presented as toolbars, mouse-overs, screen-tips, pan/zoom, scroll bars, pull-down menus	Extensive set of features for image manipulation, presented as toolbars, mouse-overs, screen-tips, pan/zoom, scroll bars, pull-down menus:
	• Pan/zoom, magnify, maximize and minimize image displays. • Scroll through slice stack • Adjust window level, contrast, brightness • Single image ROI placement, automated 2D ROI copy. ROI edit functions. • 2D Velocity Color Map	• Pan/zoom, magnify, maximize and minimize image displays. • Scroll through slice stack • Adjust window level, contrast, brightness • Single image ROI placement, automated 2D ROI copy. ROI edit functions. 2D Velocity Color Map
Scan quality assessments		
Expected Format	• Expected format is DICOM, must receive DICOM compliant image studies. • Only lossless compression.	• Expected format is DICOM, must receive DICOM compliant image studies. • Only lossless compression.
User Base	Intended to be used to support qualified cardiologist, radiologist or other licensed professional healthcare practitioners for clinical decision making.	Intended to be used to support qualified cardiologist, radiologist or other licensed professional healthcare practitioners for clinical decision making.

Summary of Testing

Nonclinical verification and validation test results established that the device meets its design requirements and intended use, and that it is as safe, as effective, and performs as well as the predicate device and that no new issues of safety and effectiveness were raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MedVoxel Systems, Inc.
% Ms. Bonnie Sewlochan
Regulatory Consultant
Bolynn Corp.
2867 Crosscurrent Drive, Mississauga
Ontario, L5N 6L1
CANADA

APR 12 2011

Re: K103565
Trade/Device Name: MedVoxel HeartPro Software Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: April 4, 2011
Received: April 7, 2011

Dear Ms. Sewlochan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K103565

Device Name: MedVoxel HeartPro Software Application

Indications for Use:

HeartPro consists of software that analyzes DICOM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. *HeartPro* specifically analyzes the blood flow to the heart and its major vessels using multi-slice, multi-phase and velocity encoded MR images. It provides clinically relevant and reproducible, quantitative data and has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners.

The data produced by *HeartPro* is intended to be used to support qualified cardiologist, radiologist or other licensed professional healthcare practitioners for clinical decision making. It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____

(per 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103565